310-DD COVERED TRANSPLANTS AND RELATED IMMUNOSUPPRESSANT MEDICATIONS

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Overview. For adults, organ transplant services are not mandatory covered services under Title XIX, and each State has the discretion to choose whether or not transplants will be available to members. The AHCCCS Administration, as the single State agency, has the authority under Federal law to determine which transplant procedures, if any, will be reimbursed as covered services.

When a State elects to cover transplant services, Federal law 42 USC §1396b(i) limits Federal financial participation to only those organ transplant procedures with written standards of coverage described in the State Plan. Additionally, Federal provisions authorize the Title XIX agency to impose limits on transplant services based on medical necessity and to place restrictions on the facilities and practitioners performing organ transplant procedures as long as they are consistent with accessibility to high quality care (Title 42 of the Code of Federal Regulations [42 CFR] 441.35).

However, the Early and Periodic Screening Diagnostic and Treatment (EPSDT) Program for individuals under age 21 covers all non-experimental transplants necessary to correct or ameliorate defects, illnesses and physical conditions whether or not the particular non-experimental transplant is covered by the AHCCCS State Plan.

AHCCCS covers medically necessary transplantation services and related immunosuppressant medications in accordance with Federal and State law and regulations.

The solid organ and tissue transplant services described in this policy, including the relevant standards of coverage, are referenced in the AHCCCS State Plan. The AHCCCS State Plan is the document approved by the Federal government which outlines the eligibility requirements and covered services for the AHCCCS program.

As with other AHCCCS-covered services, transplants must be medically necessary, cost effective, Federally reimbursable and State reimbursable. Arizona State regulations specifically address transplant services and related topics, as follows:

1. Non-experimental transplants which are approved for Title XIX reimbursement are covered services (Arizona Revised Statute [A.R.S.] §36-2907).

2. Services which are experimental, or which are provided primarily for the purpose of research are excluded from coverage (Arizona Administrative Code [A.A.C.] R9-22-201).

3. Medically necessary is defined as those covered services "provided by a physician or other licensed practitioner of the healing arts within the scope of practice under State law to prevent disease, disability or other adverse health conditions, or their progression, or prolong life" (A.A.C. R9-22-101).

4. Experimental services are defined as "services associated with treatment or diagnostic evaluation and that are not generally and widely accepted as standard of care in the practice of medicine in the United States unless:

    a. The weight of the evidence in peer-reviewed articles in medical journals published in the United States supports the safety and effectiveness of the service, or

    b. In the absence of peer-reviewed articles, for services that are rarely used, novel or relatively unknown in the general professional medical community, the weight of opinions from specialists who provide the service attests to the safety and effectiveness of the service". (A.A.C. R9-22-101)

    c. Standard of care is defined as "a medical procedure or process that is accepted as treatment for a specific illness, injury or medical condition through custom, peer review or consensus by the professional medical community" (A.A.C. R9-22-101).

In developing this Policy, the AHCCCS Administration has consulted with transplant experts to develop criteria for transplant coverage consistent with the current body of medical literature, including United Network for Organ Sharing (UNOS) clinical standards for solid organ transplant procedures, the Foundation for the Accreditation of Cellular Therapy (FACT) as well as peer-reviewed articles in medical journals published in the United States.

It is the AHCCCS Administration's position that the criteria delineated in this Policy represent current accepted transplant medical knowledge and the current standard of care in the professional transplant community for determining when transplants are medically

necessary, cost-effective, and not primarily for purposes of research. Emerging technologies and advances in medical treatments will likely alter the standards set forth in this Policy. In light of the evolving body of transplant knowledge, it is expected that each AHCCCS Contractor will consult with the current authoritative medical sources to determine whether a particular transplant is medically necessary, cost-effective, non-experimental, and not primarily for purposes of research. The AHCCCS Contractor shall provide the medical justification for the decision that is made. The Contractor has access to and may consult with the transplantation management entity (AHCCCS consultant) under contract with AHCCCS. Although the Contractor is encouraged to consult with the AHCCCS consultant for guidance in those cases requiring such medical determinations, the Contractor is not required to do so. Contractors not using the AHCCCS consultant must obtain their own expert opinion.

Definitions.

Close Proximity means within the geographic service area.

Hematopoietic Transplants means blood based transplants specifically relating to bone marrow, stem cell and lymphocyte infusions.

Description. The Transplant Policy sets forth criteria, including indications and contraindications, for determining whether transplant services are medically necessary, cost effective, non-experimental, and not primarily for purposes for research. Contraindications are conditions which may significantly adversely impact the outcome of the transplant. They are not regarded as an absolute bar to transplantation. Contraindications must be evaluated along with all other relevant factors to determine whether the transplant service is medically necessary, non-experimental, and not primarily for purposes of research in each particular case.

Both general and organ/tissue specific contraindications and indications are listed in this policy. General contraindications and indications are found under the heading "Solid Organ and Tissue Transplants and Related devices: Indications and Contraindications / Limitations." This Policy also describes some of the general medical conditions which must be considered to determine the appropriateness of the transplant. The general medical conditions that must be evaluated in establishing the medical necessity and the non-experimental nature of the transplant service are found under the heading "General Medical Conditions that Must be Considered".

1. Transplant Services and Settings

   Transplant services are covered only when performed in specific settings:

   a. Solid organ transplantation services must be provided in a CMS certified transplant center that is contracted with AHCCCS and that is also a UNOS approved transplant center, unless otherwise approved by the member's Contractor, and/or the AHCCCS Chief Medical Officer (CMO), Medical Director or designee.

   b. Hematopoietic transplant services must be provided in a facility that has achieved accreditation and is contracted with AHCCCS, unless otherwise approved by the member's Contractor, and/or the AHCCCS Chief Medical Officer (CMO), Medical Director or designee.

   Transplantation related services and immunosuppressant drugs are not covered services for individuals in the Federal Emergency Services (FES) Program, pursuant to 42 USC 1396b(v)(3) and A.A.C. R9-22-206. Persons who qualify for transplant services, but who are later determined ineligible under A.R.S. 36-2907.10 due to excess income may qualify for extended eligibility (refer to Attachment A). For information about transplants and reinsurance, refer to the AHCCCS Contract.

2. Assessment for Transplant Consideration

   The first step in the assessment for transplant consideration is the initial evaluation by the member's PCP and/or the specialist treating the condition necessitating the transplant. In determining whether the member is appropriate for referral for transplant consideration, the PCP/specialist must determine that all of the following conditions are satisfied:

   a. The member will be able to attain an increased quality of life and chance for long-term survival as a result of the transplant

   b. There are no significant impairments or conditions that would negatively impact the transplant surgery, supportive medical services, or inpatient and outpatient post-transplantation management of the member

   c. There are strong clinical indications that the member can survive the transplantation procedure and related medical therapy (e.g., chemotherapy, immunosuppressive therapy)

d. There is sufficient social support to ensure the member's compliance with treatment recommendations such as, but not limited to, immunosuppressive therapy, other medication regimens and pre- and post-transplantation physician visits. For a pediatric/adolescent member, there is adequate evidence that the member and parent/guardian will adhere to the rigorous therapy, daily monitoring and re-evaluation schedule after transplant

e. The member has been screened for potential co-morbid conditions that may impact the success of the transplant. For example, all age appropriate routine screenings such as mammograms and colonoscopies are current, and

f. The member's condition has failed to improve with other conventional medical/surgical therapies. This information must be documented and submitted to the Contractor at the time of request for evaluation.

3. AHCCCS Covered Solid Organ and Tissue Transplants

The following solid organ and tissue transplants are AHCCCS covered services when medically necessary, cost effective, non-experimental, and not primarily for purposes of research. Live donor/kidney transplants are covered for pediatric and adult members. Live donor transplants may be considered on a case-by-case basis for solid organs other than kidney when medically appropriate and cost effective. AHCCCS and its contractors are only responsible for donor related costs in cases of pediatric/adult kidney transplants and pediatric liver transplants. Detailed criteria regarding specific transplants are found under the heading "Solid Organ and Tissue Transplants and Related Devices: Indications and Contraindications/Limitations."

a. Heart

b. Heart/Lung

c. Lung – single and double

d. Liver (cadaveric and living – note: living are only covered for pediatric members)

e. Kidney (cadaveric and live donor)

f. Simultaneous Pancreas/Kidney and Pancreas after Kidney

g. Small bowel transplantation (pediatric members only)

h. Liver (cadaveric or living)/small bowel (pediatric members only)

i. Pancreas retransplantation

j. Hematopoietic transplants

1) Bone Marrow

a) Allogeneic (related and unrelated)

b) Autologous

2) Related and unrelated cord blood hematopoietic stem cell (for specific diagnoses)

3) Donor Lymphocyte Infusion (DLI)

k. Tandem hematopoietic transplants or double organ transplantation consisting of multiple of the above covered organs is covered

4. Other transplants and devices included in this Policy are:

a. Ventricular Assist Device (VAD) is an AHCCCS covered service when used as a bridge to transplantation and other specific criteria are met. Refer to "Solid Organ and Tissue Transplants and Related Devices: Indications and Contraindications/Limitations" within this Policy section for more details.

b. Bone grafts and corneal transplants are AHCCCS covered services.

Amount, Duration and Scope. Coverage of transplantation services includes the following components of service, as required by the specific type of transplantation:

1. For the transplant recipient and donor:

a. Pre-transplant evaluation (inpatient or outpatient), which includes, but is not limited to, the following:

1) Physical examination

2) Psychological and social service evaluations

3) Laboratory studies including HLA typing and current laboratory studies for infectious processes that may affect the long term success of the transplant

4) X-rays and diagnostic imaging, and

5) Biopsies

b. Medically necessary post-transplant care (inpatient and outpatient), which may include, but is not limited to, the following:

1) Laboratory studies

2) X-rays and diagnostic imaging

3) Biopsies, and

4) Treatment of complications

2. Additional covered services for the transplant recipient only:

a. Nutritional assessment

b. Dental evaluation and treatment for oral infection. For adults, this service is limited to diagnosis and treatment for the elimination of oral infection, and will commence only after the member has been established as an otherwise appropriate candidate. Other dental services, including, but not limited to, restorative and cosmetic dentistry, will not be covered. Medically necessary and cost effective dental care is covered for individuals under age 21 to correct or ameliorate defects, illnesses and physical conditions under the EPSDT Program.

c. Pre-transplant inpatient and outpatient donor search

d. Room and board for the transplant recipient and, if needed, one adult caregiver during the time it is necessary for the member to remain in close proximity to the transplant center

e. Hospitalization from the date of admission for the transplant to discharge

f. Transportation for the transplant recipient and, if needed, one adult caregiver to and from medical treatment during the time it is necessary for the member to remain in close proximity to the transplant center

g. All related medications, including immunosuppressants. **Note:** AHCCCS is the secondary payer of immunosuppressant medications if the member is also a Medicare beneficiary and is eligible to receive the immunosuppressant medications under either Medicare Part B or Part D.

h. Post-transplant discharge evaluations

3. Additional covered services for the donor:

1. Inpatient or outpatient donor organ, tissue or cell procurement, processing and storage

2. Preparation and transplantation services from date of admission through day of transplant, and

3. Post-transplant follow-up visits.

A. GENERAL CONTRAINDICATIONS

General contraindications to solid organ and tissue transplantation include, but are not limited to:

1. History of non-compliance or psychiatric condition(s) such that there is an inability to comply with an immunosuppression protocol

2. HIV positive status and viral load – members whose HIV status makes them ineligible for AHCCCS coverage of transplantation have the potential to enroll in one of the National Institute of Health's approved clinical trials. These transplants are subject to the policy described in the section of this policy entitled "Medically Necessary Services for Members who Receive Transplants that are Not Covered by AHCCCS".

3. Active malignancy (other than hepatocellular carcinoma for liver transplants) or prior metastatic disease within the past five years. This is a contraindication to solid organ transplant. However, it is not a contraindication to hematopoietic stem cell transplant.

4. The failure of more than two organs. This does not include instances where the failure of one organ is secondary to the failure of another organ.

5. Presence of active infection other than that which has caused the underlying organ failure. For example, established cirrhosis with active viral infection is considered a general contraindication to an isolated kidney transplant.

6. Active substance abuse or history of substance abuse in the last six months (if there is an urgent need, evaluation only may be allowed on a case-by-case basis).

7. Lack of a support system, which, based on the member's condition and general health, would place the success of the transplant at risk.

B. GENERAL MEDICAL CONDITIONS WHICH MUST BE CONSIDERED

The general medical conditions that must be evaluated prior to transplant to determine whether a particular transplant is medically necessary, cost effective, non-experimental, and not primarily for purposes of research include, but are not limited to:

1. Morbid obesity (body mass index [BMI] of > 39 kg/m^2). This consideration applies to solid organ transplants except for liver transplants for hepatocellular carcinoma.

2. For members with a history of substance abuse, six months of current, ongoing attendance in an approved substance abuse program, plus a patient-signed contract, sponsor and paper documentation of attendance in the program are required prior to determination for transplant listing. For members with a remote history of substance abuse (greater than three years prior), attendance in an approved substance abuse program may be waived. All members with a history of substance abuse must have three consecutive negative random screens reported by the PCP and/or specialist prior to the referral to the transplant facility for evaluation. In addition, the member will be monitored with random and repeated alcohol and/or drug screening during the assessment process up to the time of the transplant.

3. Comorbid conditions (e.g., systemic lupus erythematosis, cystic fibrosis, sarcoidosis) are relative contraindications, based on the severity of the disease.

C. SOLID ORGAN AND TISSUE TRANSPLANTS AND RELATED DEVICES: SPECIFIC INDICATIONS AND CONTRAINDICATIONS/LIMITATIONS

1. Heart

Prior to heart transplant, all other medical and surgical therapies which might be expected to yield both short- and long-term survival (3 to 5 years) must have been tried or considered.

a. Indications

Criteria for medical necessity of heart transplantation include, but are not limited to, the following indications:

1) End-stage heart disease

2) Ischemic myocardial disease

3) Idiopathic Cardiomyopathy

4) Valvular disease

5) Congenital cardiac disease

6) Myocardial disease (e.g., sarcoidosis and amyloidosis)

7) Drug-induced myocardial destruction due to prescription medication

8) Class IV cardiac disease when surgical or medical therapy is not pertinent and estimated survival is less than 6 to 12 months without a transplant

b. Contraindications

In addition to the general contraindications noted in Section A of this Policy, the following are contraindications to heart transplantation:

1) Severe pulmonary hypertension

2) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible

3) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs

4) Symptomatic peripheral or cerebral vascular disease

5) Chronic obstructive pulmonary disease or chronic bronchitis

6) Recent and unresolved pulmonary infarction

7) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, which required multi-drug therapy for even moderate control (for patients who would be on cyclosporine protocols)

8) Cachexia, even in the absence of major end-organ failure

9) The need for or prior transplantation of another organ such as lung, liver, kidney or hematopoietic transplants, or

10) The use of a donor heart which may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or preexisting disease.

c. Other Factors

Other factors which may be considered contraindications include, but are not limited to:

1) Insulin-dependent diabetes mellitus with end-organ disease

2) Severe peripheral or cerebrovascular disease

3) Documented peptic ulcer disease, or

4) Current or recent history of diverticulitis.

2. Ventricular Assist Device (VAD)

AHCCCS covers Ventricular Assist Devices (VADs) as a bridge to heart transplant only, for eligible members when medically necessary, cost effective, non-experimental, and not primarily for purposes of research and when the device is used in accordance with the Food and Drug Administration (FDA) approved labeling instructions.

AHCCCS-contracted transplant center surgeons use their skill and judgment to select the appropriate assist device, based on:

- Degree and presentation of cardiac insufficiency
- Size of recipient, and
- Device capability.

a. VAD Criteria

Medical necessity for VADs as a bridge to transplant is based on the following criteria:

1) Adult Member

The potential **adult** recipient must meet **all** of the following:

a) Has been accepted and listed for cardiac transplantation

b) Is experiencing end stage heart failure with progressive failure to respond to medical management and meets the definition of cardiogenic shock, manifested by any two of the following:

(1) Cardiac index < 2.0 liters/m^2/min

(2) Need for at least two inotropes and unable to wean

(3) Systemic vascular resistance >2100 dyn/sec/cm^2

(4) Atrial pressure > 20 mm Hg

(5) Right atrial pressure > 16 mm Hg, pulmonary capillary wedge pressure (PWCP) >16 mm Hg

(6) Systemic hypotension (systolic pressure < 80 mm Hg)

(7) Urine output < 20 mL/hr, or

(8) Metabolic acidosis

2) Pediatric Member

The potential **pediatric** recipient must meet **all** of the following:

a) Has been accepted and listed for cardiac transplantation

b) Must meet the age restrictions established by the FDA for the particular device used

c) Has a body surface area (BSA) $\geq 0.7m^2$ and $< 1.5\ m^2$

d) Is in New York Heart Association class IV end-stage heart failure, and

e) Is refractory to medical therapy.

b. Contraindications

Contraindications to successful VAD transplantation and subsequent recovery include, but are not limited to:

1) Severe lung disease, except as appropriate for heart-lung transplantation (refer to the sections pertaining to lung and heart-lung transplantation in this Policy)

2) Malignant disease

3) Stroke or refractory hypertension

4) Chronic pulmonary embolism or recent pulmonary infarction, except as appropriate for heart-lung transplantation (refer to the sections pertaining to lung and heart-lung transplantation in this Policy)

5) Active infection

6) Irreversible disease of a major organ system, or

7) Critical psychosocial conditions, behaviors or problems in adherence to a disciplined medical regimen which preclude a positive transplant outcome.

3) Lung

a) Indications

Criteria for medical necessity for lung transplantation in include, but are not limited to, the following indications:

1) Alpha-1 antitrypsin deficiency

2) Primary pulmonary hypertension

3) Pulmonary fibrosis, idiopathic pulmonary fibrosis

4) Bilateral bronchiectasis

5) Cystic fibrosis (both lungs to be transplanted)

6) Bronchopulmonary dysplasia

7) Eisenmenger's syndrome

8) Sarcoidosis lung involvement

9) Scleroderma

10) Lymphangiomyomatosis

11) Emphysema

12) Eosinophilia granuloma

13) Pulmonary hypertension due to cardiac disease, or

14) Idiopathic fibrosing alveolitis.

b) Contraindications

In addition to the general contraindications noted in Section A of this Policy, contraindications to lung transplantation, include, but are not limited to:

1) Primary or metastatic malignancies of the lung

2) Acute respiratory insufficiency or failure

3) End-stage pulmonary disease with limited life expectancy

4) Abscess of lung and mediastinum

5) Current significant acute illness that is likely to contribute to a poor outcome if the patient receives a lung transplant or current use of mechanical ventilation for more than a brief period

6) Chronic pulmonary infection in candidates for single lung transplantation

7) Continued cigarette smoking or failure to have abstained for long enough to indicate low likelihood of recidivism

8) Systemic hypertension that requires more than two drugs for adequate control

9) Inadequate biventricular cardiac function, significant coronary artery disease

10) Cachexia, even in the absence of major end-organ failure

11) Previous thoracic or cardiac surgery or other basis for pleural adhesions

12) Chronic cortisone therapy or recent therapeutic use of systemic steroids, and

13) System-wide involvement of cystic fibrosis

4. Heart and Lung

a. Indications

Criteria for medical necessity for heart/lung transplantation include, but are not limited to, the following indications:

1) Irreversible primary pulmonary hypertension with congestive heart failure

2) Non-specific pulmonary fibrosis

3) Eisenmenger complex with irreversible pulmonary hypertension and heart failure

4) Cystic fibrosis with severe heart failure

5) Emphysema with severe heart failure, or

6) Chronic obstructive pulmonary disease (COPD) with severe heart failure

b. Contraindications and General Medical Considerations

Refer to the individual heart and lung sections in this Policy for contraindications and general medical considerations

5. Liver

a. Indications: **Adult and Pediatric** Liver Transplants

Criteria for medical necessity for liver transplantation in adults and pediatric liver transplants (except as otherwise indicated) include, but are not limited to, the following indications:

1) Fulminant hepatic failure – This is an emergent basis for transplant (viral [A, B and Non-A-Non-B], toxins, drugs, Wilson's Disease, idiopathic).

2) Primary/secondary biliary cirrhosis

3) Primary sclerosing cholangitis

4) Cryptogenic or autoimmune cirrhosis

5) Chronic active hepatitis due to Hepatitis B, C or delta hepatitis

6) Alcoholic liver disease after a period of abstinence of six months or more

7) Alpha-1 antitrypsin deficiency

8) Wilson's Disease

9) Primary hemochromatosis

10) Protoporphyria

11) Familial cholestasis (Byler's disease)

12) Trauma

13) Drug- or toxin-induced liver disease (including but not limited to iatrogenic origin)

14) Extrahepatic biliary atresia, intrahepatic bile duct paucity (Alagille's syndrome), as well as obstructive cholestasis

15) Budd-Chiari syndrome

16) Biliary dysplasia

17) Metabolic liver disorders

18) Cholangiocarcinoma (for adults: when a transplant center applies for a meld exception for unresectable cholangiocarcinoma based on underlying liver disease or due to technical considerations, mass < 3 cm. and with intrahepatic and extrahepatic metastases excluded)

19) Hepatocellular carcinoma (HCC) when the following conditions are met:

a) The member is not a candidate for subtotal liver resection

b) The member has a single tumor less than or equal to 5 cm in diameter, or has less than three tumors that all are less than or equal to 3 cm in diameter, and

c) There is no macrovascular involvement or identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bones.

20) Retransplantation when the following occurs:

a) Chronic rejection

b) Biliary stricture

c) Hepatic artery thrombosis

d) Graft thrombosis

e) Sickle cell hepatopathy

f) Hepatic veno occlusive disease

b. Indications: Limited to Pediatric Transplants

Criteria for medical necessity for liver transplantation limited to the **pediatric** population include, but are not limited to, the following indications:

1) Intractable cholestasis, intrahepatic (iopathic neonatal hepatitis)

2) Portal hypertension

3) Multiple episodes of ascending cholangitis

4) Failure of synthetic function

5) Failure to thrive, malnutrition

6) Intractable ascites

7) Encephalopathy

8) Caroli's with CHF

9) Cystic fibrosis

10) Metabolic defects for which liver transplantation will reverse life-threatening illness and prevent irreversible central nervous system (CNS) damage. The following may be underlying diagnoses/disorders that lead to pediatric liver transplantation:

    a) Urea cycle defects

    b) Selected organic acidemias

    c) Crigler-Najjar Syndrome

    d) Familial hypercholesterolemia

    e) Neonatal iron storage disease

    f) Hyperoxaluria Type I

    g) Hemophilia A and B

    h) Tyrosinemia

    i) Glycogen storage disease (I, III, IV)

    j) Glycogen debrancher deficiency 1B

    k) Disorders of bile acid metabolism

    l) Lipid storage disease, and

    m) Protein C Deficiency.

11) Malignancy including but not limited to:

a) Hepatoblastoma

b) Hepatocellular carcinoma

c) Hemangioendothelioma

d) Sarcomas, and

e) Neuroendocrine tumors when the tumor does not extend beyond the margins of the liver.

c. Contraindications Limited to Adults

In addition to the general contraindications noted in Section A of this Policy, contraindications to liver transplantation in **adults**, include, but are not limited to:

1) Malignancies, other than HCC with the criteria previously stated in this Section

2) Acute severe hemodynamic compromise at the time of transplant if accompanied by compromise or failure of one or more vital organs

3) The need for prior transplantation of another organ such as lung, kidney, heart or blood or marrow if this represents a co-existence of significant disease

4) Insulin-dependent diabetes mellitus with end-organ disease

5) Gross vascular invasion of hepatocellular carcinoma, or

6) Systemic diseases that will result in member death regardless of liver transplant

d. Contraindications Limited to Pediatric Liver Transplants

In addition to the general contraindications noted in Section A of this Policy, contraindications to liver transplantation in the **pediatric** population include, but are not limited to:

1) Persistent viremia

2) Active sepsis

3) Severe cardio-pulmonary comorbidities

4) Severe neurological disorder

5) Gross vascular invasion of hepatocellular carcinoma

6) Malignancy extending beyond the margins of the liver with exception of neuro-endocrine tumors metastatic into the liver, and

7) Systemic diseases that will result in member death regardless of liver transplant

6. <u>Kidney</u>

a. Indications

Criteria for medical necessity for live donor or cadaveric kidney transplantation includes, but is not limited to, the following indications:

1) Chronic renal failure

2) Impending long-term dialysis

3) End stage renal disease which may arise from the following conditions:

a) Glomerulonephritis

(1) Proliferative

(2) Membranous

(3) Mesangio-capillary

b) Chronic Pyelonephritis

c) Hereditary conditions

(1) Polycystic disease

(2) Medullary cystic disease

(3) Nephritis (including Alport's syndrome)

d) Hyperactive nephrosclerosis

e) Metabolic conditions

(1) Cystinosis

(2) Amyloid

(3) Gout

f) Congenital conditions

(1) Hyperplasia

(2) Horseshoe kidney

g) Toxic conditions

(1) Analgesic nephropathy

(2) Heavy metal poisoning

h) Irreversible acute renal failure

(1) Cortical necrosis

(2) Acute tubular necrosis

b. Indications Limited to the Pediatric Population

For **pediatric** kidney transplants, additional criteria for transplantation include, but are not limited to:

1) Wilm's tumor (non-metastatic), and

2) Oxalosis (may also require a liver-kidney transplant and will be considered on a case-by-case basis).

c. Contraindications

In addition to the general contraindications noted in Section A of this Policy, contraindications to kidney transplantation include, but are not limited to:

1) Potential complications from immunosuppressive regimens are unacceptable to the member (the benefits of remaining on dialysis outweigh the risks of transplantation)

2) Hepatitis C infection, and

3) Problems or abnormalities with the lower urinary tract.

d. Living Kidney Donor Exclusion Criteria

1) In order to qualify as a living kidney donor, the donor must be at least 18 but not more than 65 years of age.

2) In addition, the donor will not be considered if he/she has any of the following:

a) Hypertension (>140/90 or requires medication)

b) Diabetes or abnormal glucose intolerance test

c) Proteinuria >250 mg/24 hours

d) Recent or recurrent kidney stones

e) Abnormal glomerular filtration rate, creatinine clearance <80 mL/min

f) Microscopic hematuria

g) Urologic abnormalities in donor kidney

h) Significant co-morbid medical conditions, (e.g., malignancy, COPD, etc.)

i) Obesity (30% over ideal body weight), see Appendix I for BMI charts

j) History of thrombosis or thromboembolism, or

k) Psychiatric contraindications including active substance abuse.

7. Simultaneous Pancreas/Kidney and Pancreas After Kidney

Covered services are limited to total pancreas only. Partial pancreas and islet cell transplantations are not covered because the medical efficacy of such transplants has not been demonstrated. Islet cell transplantation may be available under clinical research through the National Institutes of Health.

Note: Pancreas only transplants are covered for retransplantation when a previously transplanted pancreas has failed and the member meets the criteria for retransplantation in Number 8 of this Section.

a. Indications for Simultaneous Pancreas/Kidney Transplantation

Criteria for medical necessity for simultaneous pancreas/kidney transplantation include, but are not limited to, the following indications:

1) Insulin-dependent diabetes mellitus with impending renal failure, and

2) The patient is an acceptable candidate for pancreas transplantation and has no living kidney donor available.

b. Indications for Pancreas After Kidney Transplantation

Criteria for medical necessity of pancreas after kidney transplantation include, but are not limited to:

1) Achievement of adequate renal function post kidney transplantation, and

2) Extreme labile Type I diabetes that is not amenable to other treatments such as an insulin pump.

c. Contraindications

In addition to the general contraindications noted in Section A of this Policy, contraindications to simultaneous pancreas/kidney transplantation and pancreas after kidney transplantation include, but are not limited to:

1) Uncorrectable cardiovascular disease

2) Ejection fraction <30%

3) Peripheral vascular disease that is not correctable

4) Active substance abuse, or

5) End-organ disease, in other than pancreas or kidney, secondary to insulin-dependent diabetes mellitus.

8. Pancreas Only (Retransplantation)

"Pancreas only" transplants are covered for retransplantation when a previously transplanted pancreas has failed and the member meets the criteria noted below. The retransplantation must be performed at an AHCCCS contracted center that meets the same criteria as an accredited and certified kidney transplant center.

Member criteria specific to pancreas retransplantation include:

1) Documented pancreas organ failure

2) Documented medically uncontrollable labile insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization

3) Hospitalizations related to complications due to frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring hypoglycemic attacks, and

4) Management by an endocrinologist for a minimum of 12 months with the most medically recognized advanced insulin formulations and delivery systems, including insulin pump therapy if appropriate.

9. Small Bowel

Note: Small bowel transplantation is limited to members who are under 21 years of age and meet the medical eligibility criteria.

a. Indications

Criteria for small bowel (SB) transplantation alone, and combined small bowel/liver transplantation (SB/LT) include, but are not limited to the following conditions:

1) Small bowel syndrome resulting from inadequate intestinal propulsion due to neuromuscular impairment

2) Small bowel syndrome resulting from post-surgical conditions due to resections for:

a) Intestinal cysts

b) Mesenteric cysts

c) Small bowel or other tumors involving small bowel

d) Crohn's disease

e) Mesenteric thrombosis, or

f) Volvulus

3) Short-gut syndromes in which there is liver function impairment (usually secondary to total parenteral nutrition [TPN])

4) Impending or overt liver failure due to TPN-induced liver injury, with clinical manifestations including elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulapathy, stomal bleeding or hepatic fibrosis/cirrhosis

5) Thrombosis of two or more major central venous channels (jugular, subclavian or femoral veins)

6) Two or more episodes per year of systemic sepsis secondary to line infection, which require hospitalization, indicating failure of TPN therapy, or

7) Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.

b. Contraindications

In addition to the general contraindications noted in Section A of this Policy, contraindications to small bowel (SB) transplantation alone, and combined small bowel/liver transplantation (SB/LT), include, but are not limited to, the following conditions:

1) Insufficient vascular patency, and

2) Life-threatening and non-correctable illness not related to the digestive system such as:

a) Profound neurological disability, or

b) Chronic cardio-pulmonary disease.

10. Allogeneic Bone Marrow Transplantation

a. Criteria for medical necessity for allogeneic bone marrow transplantation (myeloablative only unless otherwise indicated) include, but are not limited to, the following indications:

1) Acute lymphocytic leukemia (ALL)

2) Acute myeloid leukemia (AML)

3) Aplastic anemia

4) Chronic myelogenous leukemia (CML)

5) Fanconi anemia (FA)

6) Hodgkin's disease (recurrence only – not as an initial treatment)

7) Metabolic storage diseases on a case-by-case basis (e.g., lysosomal storage diseases, metachromatic leukodystrophy, arylsulfatase A deficiency)

8) Recurrent non-Hodgkin's lymphoma

9) Osteopetrosis

10) Primary lethal immune deficiencies and hemophatocytic lymphohistiocytosis

(1) Wiskott-Aldrich Syndrome

(2) Severe combined immune deficiencies (SCIDS)

11) Sickle cell disease, where benefit to risk has been established for the case

12) Severe congenital anemia

13) Thalassemia

14) Myelodysplastic syndrome

15) Juvenile monomyelocytic leukemia (JMML), and

16) Primary amyloid light chain amyloidosis.

b. Contraindications

In addition to the general contraindications noted in Section A of this Policy, contraindications to allogeneic bone marrow transplantation include, but are not limited to, the following conditions:

1) Chronic life threatening, non-correctable cardio-pulmonary disease

2) Elevated transaminases found in liver function tests as this is a predictor for veno-occlusive disease (VOD)

3) Parenchymal CNS disease

4) Active or history of systemic aspergillosis, and

5) Genetic diseases -- There are no peer reviewed studies to support the efficacy of allogeneic bone marrow or hematopoietic stem cell transplant for genetic diseases at this time.

11. Autologous Bone Marrow Transplantation

a. Criteria for medical necessity for autologous bone marrow transplantation following high-dose chemotherapy [HDC] and/or radiotherapy, include, but are not limited to, the following indications:

1) Acute lymphocytic leukemia (ALL) (in patients without a suitable donor for allogeneic transplantation) (for **adults** only)

2) Acute myeloid leukemia (AML) (in patients without a suitable donor for allogeneic transplantation) (for **adults** only)

3) Germ cell tumors

4) Hodgkin's disease with responsive disease

5) Multiple myeloma (MM)

   a) Physiologic age of 60 or under

   b) A minimum of three months must elapse between transplants

   c) There must be a re-staging and assessment of response before the second transplant

6) Only patients with less than a partial or very good remission, as measured from the start of initial therapy, are good candidates for the second transplant, and melphalan-only regimen for both transplants, at a dosage range of 140-200 mg/kg

7) Neuroblastoma

8) Non-Hodgkin's lymphoma (NHL) with responsive disease, or

9) Wilm's tumor

b. Contraindications

In addition to the general contraindications noted in Section A of this Policy contraindications to autologous bone marrow transplantation include, but are not limited to, the following conditions:

1) Chronic cardio-pulmonary disease

2) Elevated transaminases found in liver function tests as this is a predictor for veno-occlusive disease (VOD)

3) Parenchymal CNS disease, and

4) Active or history of systemic aspergillosis.

12. Related and Unrelated Cord Blood

Medical necessity for cord blood transplantation (CBT) will be determined on a case-by-case basis. For any **pediatric** CBT, a single cord blood unit will be considered standard treatment.

NOTE: A single unit pediatric CBT is allowed for diseases listed under allogeneic, single unit only.

13. Donor Lymphocyte Infusion (DLI)

a. Donor lymphocyte infusion is a specific infusion of allogeneic donor-derived lymphocytes (T-cells) either harvested from blood, marrow or peripheral T-cells harvested with the use of an apheresis machine. Medical necessity for donor lymphocyte infusion may be considered in **pediatric and younger adult** members with chronic myelogeneous leukemia who experience a relapse after an allogeneic hematopoietic stem cell or bone marrow transplant or who do not respond to withdrawal of immunosuppressive medication.

b. Contraindications

In addition to the general contraindications noted in Section A of this Policy, contraindications to autologous bone marrow transplantation include but are not limited to the following conditions:

1) Chronic cardio-pulmonary disease

2) Elevated transaminases found in liver function tests as this is a predictor for veno-occlusive disease (VOD)

3) Parenchymal CNS disease, and

4) Active or history of systemic aspergillosis.

D. OUT-OF-NETWORK COVERAGE

AHCCCS provides out-of-network coverage for solid organ or stem cell and hematopoietic transplants for those members who have current medical requirements that cannot be met by an appropriate in-network transplant center. These medical requirements must be manifested as requiring either a specific level of technical expertise or program coverage that is not currently provided by AHCCCS contracted facilities. A request for out-of-network coverage will not be approved if the member has already received a medical denial from an AHCCCS contracted transplant center. The use of out-of-network transplant centers is determined by the review of quality and outcome data as published by their accreditation organization as well as their cost containment standards.

When a member completes an AHCCCS approved transplantation at an out-of-network facility, the necessary follow-up services will be covered through an AHCCCS contracted in-network facility, if one is available. These services include, but are not limited to, travel, lodging, meals, medical testing and post-operative evaluation and apply to any transplant performed under AHCCCS coverage, another third-party payer or through self-pay.

E. MULTIPLE SITE LISTING FOR SOLID ORGAN/HEMATOPOIETIC TRANSPLANTATION

If a member seeks to be evaluated for solid organ, or hematopoietic transplantation and is "listed" with more than the primary AHCCCS contracted transplant center, AHCCCS will only pay for one center's evaluation services.

In the event that a member becomes listed by a facility other than the primary AHCCCS contracted transplant center, AHCCCS will not provide coverage for any costs over and above the state-contracted rate for the specific transplant procedure.

In addition, reimbursement will be available only to FACT accredited or UNOS approved facilities. Facilities must also be CMS certified transplant centers unless otherwise approved by the member's Contractor, and/or the AHCCCS CMO, Medical Director or designee, and will be limited to the immediate hospitalization for the transplantation surgery and the inpatient post-operative care.

If a member chooses to make their own arrangements for travel, lodging and/or meals, then the member must notify the Contractor (or AHCCCS if they are a fee-for-service [FFS] member), of the arrangements they have made. In addition, the member, in such circumstances, is responsible for securing and sending appropriate medical records to the

appropriate transplant case manager. If the member is receiving services on an FFS basis through AHCCCS Administration, appropriate medical records must be sent to the transplant case manager in the AHCCCS Division of Health Care Management, Medical Management Unit.

F. MEDICALLY NECESSARY SERVICES FOR MEMBERS WHO RECEIVE TRANSPLANTS THAT ARE NOT COVERED BY AHCCCS

If a member receives a transplant that is not covered by AHCCCS, medically necessary, non-experimental services commence following discharge from the acute care hospitalization for the transplant.

1. Covered services include, but are not limited to:

   a) Transitional living arrangements appropriately prescribed for post-transplant patients

   b) Essential laboratory and radiology procedures

   c) Medically necessary post-transplant therapies

   d) Immunosuppressant medications, and

   e) Medically necessary transportation.

2. Covered services do not include:

   a) Evaluations and treatments to prepare for transplant candidacy

   b) The actual transplant procedure and accompanying hospitalization, or

   c) Organ or tissue procurement.

AHCCCS reimbursement of the Contractor for medically necessary services following non-covered organ transplantation is in accordance with the regular reinsurance guidelines found in the Reinsurance Processing Manual. AHCCCS-covered transplantation and its related medically necessary services are reimbursed in accordance with the transplant reinsurance guidelines found in the Reinsurance Processing Manual.

Refer to Policy 320-B for additional information regarding AHCCCS member participation in experimental treatment.

G. TRANSPLANTATION MANAGEMENT

The AHCCCS Administration has entered into a contract with a transplantation management entity (Consultant) to review developments, outcomes and respective changes in technology, as well as assist in the development and revision of this Policy. The Consultant will be available, as necessary, to provide expertise regarding clinical issues arising from transplant requests.

The contractor is encouraged to consult with the transplantation management entity (AHCCCS Consultant) under contract with AHCCCS for guidance in making medical determinations regarding transplants. Contractors are not required to use the AHCCCS Consultant in reaching their medical determination. Contractors have the option of obtaining their own expert opinion. However, a written medical justification for the Contractor's decision is required in each case.

AHCCCS, in partnership with the Consultant, will provide medical expertise for specific diagnoses and medical conditions that are covered for transplantation.

Consultation may include, but is not limited to:

1. Telephone access to the Consultant Medical Director. Access will be arranged by the DHCM Medical Management Unit.

2. Regular updates on changes in experimental status of selected transplants and advances in technology and devices

3. Analysis of transplantation and related technology developments with enough information, including cost projections, to assist AHCCCS in revising this Policy as necessary, and

4. Assistance in recommendation of approved/appropriate transplant facilities, as necessary, for out-of-network coverage.

REFERENCES.

1. Attachment A of this Policy for extended eligibility process/procedure

2. Chapter 300, Policy 320-B for information regarding AHCCCS member participation in experimental treatment

3. Chapter 500 for information regarding care coordination for transplant candidates who experience an interruption of eligibility or enrollment

4. Chapter 800 for fee-for-service prior authorization requirements for providers

5. AHCCCS Division of Health Care Management, Reinsurance Processing Manual, for information regarding Contractor applications for transplantation reinsurance, and

6. The AHCCCS Contracts, including specialty contracts, for further information regarding transplants and reinsurance.